

NATROBA- spinosad suspension

ParaPRO LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NATROBA Topical Suspension safely and effectively. See full prescribing information for NATROBA Topical Suspension.

Natroba (spinosad) topical suspension, 0.9 %

For topical use

Initial U.S. Approval: 2011

INDICATIONS AND USAGE

NATROBA Topical Suspension is a pediculicide indicated for the topical treatment of head lice infestations in patients four (4) years of age and older. (1)

DOSAGE AND ADMINISTRATION

- For topical use only. Not for oral, ophthalmic, or intravaginal use. (2)
- Shake bottle well. (2)
- Apply product to dry scalp and hair using only the amount needed to cover the scalp and hair. (2)
- Rinse off with warm water after 10 minutes. (2)

Repeat treatment if live lice are seen 7 days after first treatment. (2)

DOSAGE FORMS AND STRENGTHS

Suspension: 9 mg of spinosad per gram of NATROBA Topical Suspension (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Benzyl alcohol toxicity: Not recommended in infants below the age of 6 months; potential for increased systemic absorption. (5.1)

ADVERSE REACTIONS

Most common adverse events (>1%) were application site erythema and ocular erythema. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact ParaPRO, LLC at 1-855-628-7622 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Nursing Mothers: Caution should be exercised when administered to a nursing mother. (8.3)
- Pediatric Use: Safety in pediatric patients below the age of 4 years has not been established. (8.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 1/2011

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Indication

NATROBA (spinosad) Topical Suspension is indicated for the topical treatment of head lice infestation in patients four (4) years of age and older.

1.2 Adjunctive Measures

NATROBA Topical Suspension should be used in the context of an overall lice management program:

- Wash (in hot water) or dry-clean all recently worn clothing, hats, used bedding and towels.
- Wash personal care items such as combs, brushes and hair clips in hot water
- A fine-tooth comb or special nit comb may be used to remove dead lice and nits.

2 DOSAGE AND ADMINISTRATION

For topical use only. NATROBA Topical Suspension is not for oral, ophthalmic, or intravaginal use.

Shake bottle well. Apply sufficient NATROBA Topical Suspension to cover dry scalp, then apply to dry hair. Depending on hair length, apply up to 120 mL (one bottle) to adequately cover scalp and hair. Leave on for 10 minutes, then thoroughly rinse off NATROBA Topical Suspension with warm water. If live lice are seen 7 days after the first treatment, a second treatment should be applied. Avoid contact with eyes.

3 DOSAGE FORMS AND STRENGTHS

0.9%, viscous, slightly opaque, light orange-colored suspension.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Benzyl Alcohol Toxicity

NATROBA Topical Suspension contains benzyl alcohol and is not recommended for use in neonates and infants below the age of 6 months. Systemic exposure to benzyl alcohol has been associated with serious adverse reactions and death in neonates and low birth-weight infants [*See Use in Specific Populations (8.4)*].

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in clinical practice.

NATROBA Topical Suspension was studied in two randomized, active-controlled trials (N=552) in subjects with head lice; the results are presented in Table 1.

Table 1: Selected Adverse Events Occurring in at least 1% of Subjects

Signs	Spinosad (N=552)	Permethrin 1% (N=457)
Application site erythema	17 (3%)	31 (7%)
Ocular erythema	12 (2%)	15 (3%)
Application site irritation	5 (1%)	7 (2%)

Other less common reactions (less than 1% but more than 0.1%) were application site dryness, application site exfoliation, alopecia, and dry skin.

Systemic safety was not assessed in pediatric subjects under 4 years of age as laboratory parameters were not monitored in these controlled studies.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B.

There are no adequate and well-controlled studies with NATROBA Topical Suspension in pregnant women. Studies in humans did not assess for the absorption of benzyl alcohol contained in NATROBA Topical Suspension. Reproduction studies conducted in rats and rabbits were negative for teratogenic effects. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

No comparisons of animal exposure with human exposure are provided in this labeling due to the low systemic exposure noted in the clinical pharmacokinetic study [*see Clinical Pharmacology (12.3)*] which did not allow for the determination of human AUC values that could be used for this calculation.

Systemic embryofetal development studies were conducted in rats and rabbits. Oral doses of 10, 50 and 200 mg/kg/day spinosad were administered during the period of organogenesis (gestational days 6 – 15) to pregnant female rats. No teratogenic effects were noted at any dose. Maternal toxicity occurred at 200 mg/kg/day. Oral doses of 2.5, 10, and 50 mg/kg/day spinosad were administered during the period

of organogenesis (gestational days 7 – 19) to pregnant female rabbits. No teratogenic effects were noted at any dose. Maternal toxicity occurred at 50 mg/kg/day.

A two-generation dietary reproduction study was conducted in rats. Oral doses of 3, 10, and 100 mg/kg/day spinosad were administered to male and female rats from 10-12 weeks prior to mating and throughout mating, parturition, and lactation. No reproductive/developmental toxicity was noted at doses up to 10 mg/kg/day. In the presence of maternal toxicity, increased dystocia in parturition, decreased gestation survival, decreased litter size, decreased pup body weight, and decreased neonatal survival occurred at a dose of 100 mg/kg/day.

8.3 Nursing Mothers

Spinosad, the active ingredient in NATROBA Topical Suspension is not systemically absorbed; and therefore, will not be present in human milk. However, NATROBA Topical Suspension contains benzyl alcohol, which may be systemically absorbed through the skin, and the amount of benzyl alcohol excreted in human milk with use of NATROBA Topical Suspension is unknown. Caution should be exercised when NATROBA Topical Suspension is administered to a lactating woman. A lactating woman may choose to pump and discard breast milk for 8 hours (5 half-lives of benzyl alcohol) after use to avoid infant ingestion of benzyl alcohol.

8.4 Pediatric Use

The safety and effectiveness of NATROBA Topical Suspension have been established in pediatric patients 4 years of age and older with active head lice infestation [*see Clinical Studies (14)*].

Safety in pediatric patients below the age of 4 years has not been established. NATROBA Topical Suspension is not recommended in pediatric patients below the age of 6 months because of the potential for increased systemic absorption due to a high ratio of skin surface area to body mass and the potential for an immature skin barrier.

NATROBA Topical Suspension contains benzyl alcohol which has been associated with serious adverse reactions and death in neonates and low birth-weight infants. The "gasping syndrome" (characterized by central nervous system depression, metabolic acidosis, gasping respirations, and high levels of benzyl alcohol and its metabolites found in the blood and urine) has been associated with benzyl alcohol dosages >99 mg/kg/day in neonates and low-birthweight infants. Additional symptoms may include gradual neurological deterioration, seizures, intracranial hemorrhage, hematologic abnormalities, skin breakdown, hepatic and renal failure, hypotension, bradycardia, and cardiovascular collapse.

The minimum amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birthweight infants, as well as patients receiving high dosages, may be more likely to develop toxicity [*see Warning and Precautions (5.1)*].

8.5 Geriatric Use

Clinical studies of NATROBA Topical Suspension did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

10 OVERDOSAGE

If oral ingestion occurs, seek medical advice immediately.

11 DESCRIPTION

NATROBA (spinosad) Topical Suspension, is a slightly opaque, light orange colored, viscous topical

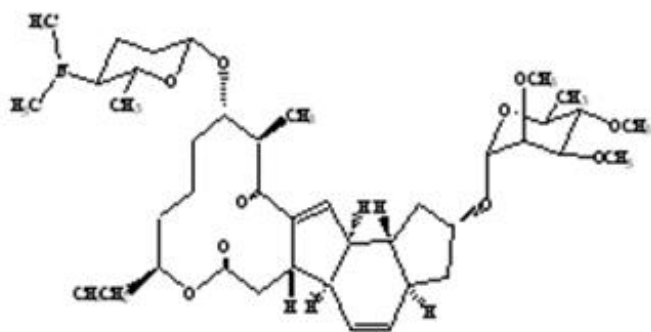
suspension.

Spinosad, the active ingredient, is derived from the fermentation of a soil actinomycete bacterium, *Saccharopolyspora spinosa*.

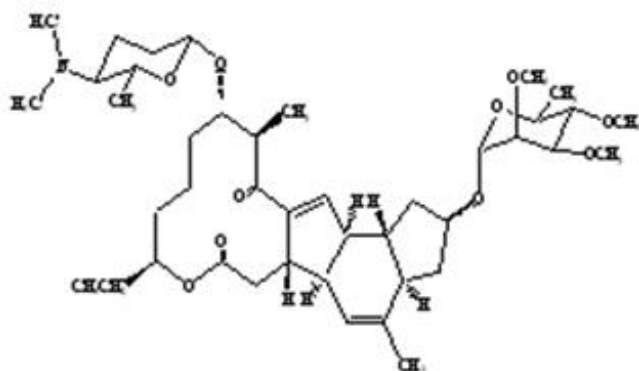
Spinosad is a mixture of spinosyn A and spinosyn D in a ratio of approximately 5 to 1 (spinosyn A to spinosyn D).

Spinosyn A: The chemical name is: 1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-2,3,4-tri-O-methyl-alpha-L-mannopyranosyl)oxy]-13-[[2R,5S,6R)-5-(dimethylamino) tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-, (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-

Spinosyn D: The chemical name is: 1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-2,3,4-tri-O-methyl-alpha-L-mannopyranosyl)oxy]-13-[[2R,5S,6R)-5-(dimethylamino) tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-, (2S,3aSR,5aS,5bS,9S,13S,14R,16aS,16bS)-



Spinosyn A (C₄₄H₅₅N₂O₁₀)
MW 731.461



Spinosyn D (C₄₄H₅₅N₂O₁₀)
MW 731.467

NATROBA Topical Suspension contains 9 mg spinosad per gram in a viscous, slightly opaque, light orange colored vehicle consisting of Water, Isopropyl Alcohol, Benzyl Alcohol, Hexylene Glycol, Propylene Glycol, Cetearyl Alcohol, Stearalkonium Chloride, Cetareth-20, Hydroxyethyl Cellulose, Butylated Hydroxytoluene, FD&C Yellow #6.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Spinosad causes neuronal excitation in insects. After periods of hyperexcitation, lice become paralyzed and die.

12.2 Pharmacodynamics

The pharmacodynamics of NATROBA Topical Suspension has not been studied.

12.3 Pharmacokinetics

An open-label, single-center study was conducted over a period of seven days to determine the pharmacokinetic profile of spinosad 1.8% in pediatric subjects with head lice infestation. Fourteen (14) subjects, 4 – 15 years of age, with head lice were enrolled into the study. All subjects applied a single topical (scalp) treatment of spinosad 1.8% for 10 minutes, after which the test article was washed off, and subjects underwent plasma sampling. Plasma samples were analyzed by a validated LC/MS/MS method. Results demonstrated that spinosad was below the limit of quantitation (3ng/mL) in all samples. The bioavailability of benzyl alcohol from NATROBA Topical Suspension is unknown as plasma concentrations of benzyl alcohol were not determined in these subjects.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of fertility

In an oral (diet) mouse carcinogenicity study, spinosad was administered to CD-1 mice at doses of 0.0025, 0.008, and 0.036% in the diet (approximately 3.4, 11.4, and 50.9 mg/kg/day for males and 4.2, 13.8, and 67.0 mg/kg/day for females) for 18 months. No treatment-related tumors were noted in the mouse carcinogenicity study up to the highest doses evaluated in this study of 50.9 mg/kg/day in male mice and 13.8 mg/kg/day in female mice. Female mice treated with a dose of 67.0 mg/kg/day were not evaluated in this study due to high mortality.

In an oral (diet) rat carcinogenicity study, spinosad was administered to Fischer 344 rats at doses of 0.005, 0.02, 0.05, and 0.1% in the diet (approximately 2.4, 9.5, 24.1 and 49.4 mg/kg/day for males and 3.0, 12.0, 30.1 and 62.8 mg/kg/day for females) for 24 months. No treatment-related tumors were noted in the rat carcinogenicity study in male or female rats up to the highest doses evaluated in this study of 24.1 mg/kg/day in male rats and 30.1 mg/kg/day in female rats. Rats in the highest dose group in this study were not evaluated due to high mortality.

Spinosad demonstrated no evidence of mutagenic or clastogenic potential based on the results of four *in vitro* genotoxicity tests (Ames assay, mouse lymphoma L5178Y assay, Chinese hamster ovary cell chromosome aberration assay, and rat hepatocyte unscheduled DNA synthesis assay) and one *in vivo* genotoxicity test (mouse bone marrow micronucleus assay).

Oral administration of spinosad (in diet) to rats, throughout mating, gestation, parturition and lactation, demonstrated no effects on growth, fertility or reproduction, at doses up to 10 mg/kg/day [*see Pregnancy (8.1)*].

14 CLINICAL STUDIES

Two multicenter, randomized, investigator-blind, active-controlled studies were conducted in 1038 subjects 6 months of age and older with head lice infestation. A total of 552 subjects were treated with NATROBA Topical Suspension. For the evaluation of efficacy, the youngest subject from each household was considered to be the primary subject of the household, and other members in the household were enrolled in the study as secondary subjects, and evaluated for all safety parameters.

In Study 1, 91 primary subjects were randomized to NATROBA Topical Suspension, and 89 primary subjects were randomized to permethrin 1%. In Study 2, 83 and 84 primary subjects were randomized to

NATROBA Topical Suspension and permethrin 1%, respectively.

In both studies, all subjects who were treated on Day 0 returned for efficacy evaluation at Day 7. Subjects with live lice present at Day 7 received a second treatment. Subjects who were lice free on Day 7 were to return on Day 14 for evaluation. Subjects with live lice and who received a second treatment were to return on Days 14 and 21.

Efficacy was assessed as the proportion of primary subjects who were free of live lice 14 days after the final treatment. Table 2 contains the proportion of primary subjects who were free of live lice in each of the two trials.

Table 2. Proportion of Subjects Free of Live Lice 14 days After Last Treatment

Study 1		Study 2	
Natroba N=91	permethrin 1% N=89	Natroba N=83	permethrin 1% N=84
77 (84.6%)	40 (44.9%)	72 (86.7%)	36 (42.9%)

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

NATROBA (spinosad) Topical Suspension, 0.9% is a slightly opaque, light orange colored, viscous liquid, supplied in 4 oz (120 mL) high density polyethylene (HDPE) bottles. NDC 52246-929-04

16.2 Storage and Handling

- Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Keep out of reach of children

17 PATIENT COUNSELING/INFORMATION

[See FDA-approved patient labeling (Patient Information)]

The patient should be instructed as follows:

- Shake bottle well immediately prior to use
- Use NATROBA Topical Suspension only on dry scalp and dry scalp hair.
- Do not swallow.
- Avoid contact with eyes. If NATROBA Topical Suspension gets in or near the eyes, rinse thoroughly with water.
- Wash hands after applying NATROBA Topical Suspension
- Use NATROBA Topical Suspension on children only under direct supervision of an adult.
- If pregnant or breastfeeding, consult a physician before use.

Patient Information

Natroba™ (Nah-TRO-buh) (spinosad) Topical Suspension, 0.9%

Important: For use on scalp hair and scalp only. Do not get NATROBA Topical Suspension in your eyes, mouth, or vagina.

Read the Patient Information that comes with NATROBA Topical Suspension before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is NATROBA Topical Suspension?

NATROBA Topical Suspension is a prescription medicine used to get rid of lice in scalp hair of children and adults.

It is not known if NATROBA Topical Suspension is safe for children under 4 years of age or in people over age 65.

Once NATROBA Topical Suspension is washed off, a fine-tooth comb may be used to remove treated lice and nits from the hair and scalp, but combing is not required. All personal items exposed to the hair or lice should be washed in hot water or dry-cleaned. See "How do I stop the spread of lice?" at the end of this leaflet.

What should I tell my healthcare provider before I use NATROBA Topical Suspension?

Tell your healthcare provider about all of your medical conditions, or the medical conditions of your child, including if you or your child:

- have any skin conditions or sensitivities
- are pregnant or planning to become pregnant. It is not known if NATROBA Topical Suspension can harm your unborn baby.
- are breastfeeding. Talk to your health care provider if you are breastfeeding.

How should I use NATROBA Topical Suspension?

- Use NATROBA Topical Suspension exactly as prescribed. Your healthcare provider will prescribe the treatment that is right for you. Do not change your treatment unless you talk to your healthcare provider.
- Use NATROBA Topical Suspension in one or two treatments that are one week apart. If live lice are seen one week (7 days) after you first used NATROBA Topical Suspension you will need to use NATROBA Topical Suspension again.
- Shake bottle well right before use.
- Use NATROBA Topical Suspension when your hair is dry. Do not wet your hair before applying NATROBA Topical Suspension.
- It is important to use enough NATROBA Topical Suspension to coat completely every single louse and to leave it on your scalp for the full 10 minutes. See the detailed Patient Instructions for Use at the end of this leaflet.
- Because you need to completely cover all of the lice with NATROBA Topical Suspension, you may need help in applying NATROBA Topical Suspension to your scalp and hair. Make sure that you and anyone who helps you apply NATROBA Topical Suspension reads and understands this leaflet and the Patient Instructions for Use.
- Children will need an adult to apply NATROBA Topical Suspension for them.
- Do not swallow NATROBA Topical Suspension. If swallowed, call your healthcare provider right away.
- Do not get into eyes. If NATROBA Topical Suspension gets in the eye, flush with water right away.
- Wash your hands after you apply NATROBA Topical Suspension.

What are the possible side effects of NATROBA Topical Suspension?

People using NATROBA Topical Suspension may have skin or eye:

- Redness
- Irritation

If skin or eye irritation happens, rinse with water right away, then call your healthcare provider or go to the emergency department

These are not all the side effects of NATROBA Topical Suspension. For more information, ask your healthcare provider.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NATROBA Topical Suspension?

- Store NATROBA in a dry place at room temperature, 20°C to 25°C (68° F to 77° F).

Keep NATROBA Topical Suspension and all medicines out of the reach of children.

What are the ingredients in NATROBA Topical Suspension?

Active ingredient: spinosad

Inactive ingredients: water, isopropyl alcohol, benzyl alcohol, hexylene glycol, propylene glycol, cetearyl alcohol, stearylalkonium chloride, cetareth-20, hydroxyethyl cellulose, butylated hydroxytoluene, FD&C yellow #6

General Information about NATROBA Topical Suspension

Medicines are sometimes prescribed for conditions other than those described in the patient information leaflets. Do not use NATROBA Topical Suspension for any condition for which it was not prescribed by your healthcare provider. Do not give NATROBA to other people, even if they have the same symptoms as you. It may harm them.

This leaflet summarizes the most important information about NATROBA Topical Suspension. If you would like more information, talk to your healthcare provider. You can also ask your healthcare provider for information about NATROBA Topical Suspension that is written for healthcare professionals.

Patient Instructions for Use

Completely cover the scalp with NATROBA Topical Suspension. Lice and nits live near the scalp. Use as much product as needed to completely cover the scalp first, and then apply outwards towards the ends of the hair.

For very thick, medium length hair or long hair, an entire bottle (120mL) of NATROBA Topical Suspension may be needed to cover the scalp and hair. Less NATROBA Topical Suspension may be needed for shorter, thinner hair.

Step 1

- Shake NATROBA Topical Suspension bottle well right before use.

Step 2



- Cover your face and eyes with a towel and keep your eyes closed tightly.
- Apply NATROBA Topical Suspension directly to **dry** hair.
- Completely cover the scalp first, and then apply outwards towards the ends of the hair.
- If not enough NATROBA Topical Suspension is used, some lice may escape treatment. It is important to use enough NATROBA Topical Suspension to cover your entire scalp and all scalp hair.

Step 3



- Allow NATROBA Topical Suspension to stay on your hair for 10 minutes. Use a timer or clock and start timing after you have completely covered your hair and scalp with NATROBA Topical Suspension.
- Continue to keep eyes covered to prevent dripping into your eyes.
- After 10 minutes, completely rinse NATROBA Topical Suspension from your hair and scalp with warm water.
- You or anyone who helps you apply NATROBA Topical Suspension should wash hands after application.
- It is okay to shampoo your hair any time after the treatment.

One week (7 days) after your first treatment, if live lice are seen, repeat the steps above.

How do I stop the spread of lice?

To help prevent the spread of lice from one person to another, here are some steps you can take:

- Avoid direct head-to-head contact with anyone known to have live, crawling lice.
- Do not share combs, brushes, hats, scarves, bandannas, ribbons, barrettes, hair bands, towels, helmets, or other hair-related personal items with anyone else, whether they have lice or not.
- Avoid sleepovers and slumber parties during lice outbreaks. Lice can live in bedding, pillows, and carpets that have recently been used by someone with lice.
- After finishing treatment with lice medicine, check everyone in your family for lice after one week. Be sure to talk to your healthcare provider about treatments for those who have lice.
- Machine-wash any bedding and clothing used by anyone having lice. Machine wash at high temperatures (150°F) and tumble in a hot dryer for 20 minutes.

This patient Leaflet has been approved by the U.S. Food and Drug Administration.

MANUFACTURED FOR:
ParaPRO LLC

Carmel, IN 46032

DISTRIBUTED BY:

ParaPRO and/or Pernix Therapeutics, Inc.

Magnolia, TX 77354

PRINCIPAL DISPLAY PANEL - 120mL Carton

NDC 52246-929-04

120mL

Rx only

NatrobaTM

(spinosad)

Topical Suspension

0.9%

**For topical use
on the scalp hair and
scalp only**



NATROBA

spinosad suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52246-929
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
spinosad (UNII: XPA88EAP6 V) (spinosad - UNII:XPA88EAP6 V)	spinosad	9 mg in 1 mL

Inactive Ingredients				
Ingredient Name				Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
HEXYLENE GLYCOL (UNII: KEH0A3F75J)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
STEARALKONIUM CHLORIDE (UNII: 0OUO26BB88)				
CETETH-20 (UNII: I835H2IHHX)				
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
WATER (UNII: 059QF0KO0R)				

Product Characteristics			
Color	ORANGE (PEARLESCENT LIGHT ORANGE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52246-929-04	1 in 1 CARTON		
1		120 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022408	01/25/2011	

Labeler - ParaPRO LLC (186639006)

Establishment			
Name	Address	ID/FEI	Business Operations
ParaPRO LLC		186639006	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Harmony Labs, Inc.		105803274	MANUFACTURE, LABEL, PACK